

FEB 11 2005

510(k) Summary of Safety and Effectiveness
Asian Intramedullary Hip Screw Nails

K 050226

Submitted by: Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116

Date: January 31, 2005

Contact Person: David Henley
Senior Regulatory Affairs Specialist

Proprietary Name: Asian Intramedullary Hip Screw Nails
Common Name: Intramedullary Hip Screw Nails and Accessories

Classification Name and Reference: 21 CFR 888.3030 - Single/multiple component metallic bone fixation appliances and accessories, Class II

Device Product Code and Panel Code: KTT and HWC / Orthopaedics / 87

Device Description:

Intramedullary Hip Screws and accessories provide an intramedullary approach to the management of fractures of the proximal femur. Devices include intramedullary nails with various diameters, lengths and neck shaft angles. The long nails are available in a right or left hand configuration. Each nail includes a 4° medio-lateral bend to allow for greater trochanteric insertion. Each nail is used with a choice of specially designed sliding lag screws or subtrochanteric lag screws in various lengths. Additional accessories are available such as a centering sleeve, a set screw, a compression screw and nail caps.

Intended Use:

Smith & Nephew, Inc. Asian Intramedullary Hip Screws are indicated for intracapsular fractures of the femoral neck; trochanteric or subtrochanteric fractures; osteotomies for patients with diseases or deformities of the hip; hip arthrodesis; supracondylar fractures and distal femoral fractures using a supracondylar plate; ipsilateral femoral shaft/neck fractures; intertrochanteric fractures; femoral neck fractures; subcapital fractures; comminuted neck and shaft fractures; femur reconstruction following tumor resection; leg length discrepancies secondary to femoral inequality; and prophylactic nailing of impending pathologic fractures. Asian Intramedullary Hip Screws and accessories are for single use only.

Technological Characteristics:

The principle of operation of the subject devices is identical to that of the predicates. There are no changes in intended use, performance specifications or method of operation. A review of the test data for the subject devices indicates that they are equivalent to the predicate devices currently in clinical use and are capable of withstanding expected *in vivo* loading without failure.

Substantial Equivalence Information:

Substantial equivalence for the Asian Intramedullary Hip Screw is based on its similarities in indications for use, design features, operational principles, and material composition when compared to the predicate devices cleared under the following submissions: **K040656**, Smith & Nephew Intramedullary Hip Screw; **K993289**, Smith & Nephew Trauma Internal Fixation System; **K040212**, TriGen InterTAN Nail System; and **K952697**, Ti Classic Compression Hip Screw.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 11 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. David Henley
Senior Regulatory Affairs Specialist
Smith & Nephew, Inc.
Orthopedic Division
1450 Brooks Road
Memphis, Tennessee 38116

Re: K050226

Trade/Device Name: Asian Intramedullary Hip Screw
Regulation Number: 21 CFR 888.3030, 21 CFR 888.3040
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories, Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC, KTT
Dated: January 31, 2005
Received: February 1, 2005

Dear Mr. Henley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

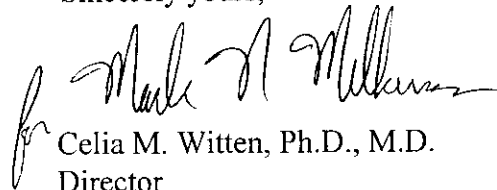
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. David Henley

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): _____

Device Name: Asian Intramedullary Hip Screw

Indications for Use:

Intramedullary Hip Screws are indicated for intracapsular fractures of the femoral neck; trochanteric or subtrochanteric fractures; osteotomies for patients with diseases or deformities of the hip; hip arthrodesis; supracondylar fractures and distal femoral fractures using a supracondylar plate; ipsilateral femoral shaft/neck fractures; intertrochanteric fractures; femoral neck fractures; subcapital fractures; comminuted neck and shaft fractures; femur reconstruction following tumor resection; leg length discrepancies secondary to femoral inequality; and prophylactic nailing of impending pathologic fractures.

Asian Intramedullary Hip Screws and accessories are for single use only.

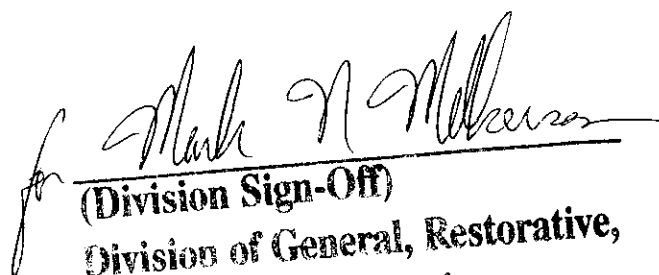
Prescription Use X
(Per 21 CFR 801, 109)

and/or

Over-the-Counter Use _____
(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K050226